CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

1.1 The purpose of this standard operating procedure (SOP) is to provide guidance to Cardinal Health employees in the Quality and Regulatory Affairs (QRA) department on responding, detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about releasing or cutting orders that are suspicious or exceed a threshold.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which DEA holds distributors responsible.

2.0 SCOPE

This procedure applies when an order is triggered by the Cardinal Health Anti-Diversion Centralization (or equivalent) system for review by the QRA Pharmacist Group in order for the QRA Pharmacist to evaluate the order so as to meet the purpose of the procedure mentioned in §1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx"~~ }	Daily Threshold Reporting
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled~~	SOM Threshold Limits

DEFENDANT EXHIBIT
CAH-WV-00073

%20Document%20Library/CAD-C002.docx" }	
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx" }	On-Site QRA and Surveillance Investigations
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }	Large Volume – Tactical and Analytical Committee Periodic Review Process
Reference 1	QRA Memo: Policy For Conducting Detail Review Of Suspicious Orders (includes analysis of totality of circumstances per May 14, 2012 Memorandum of Agreement)
Reference 2	QRA Memo: Policy For Setting Threshold Limits For Drug Families of Interest

4.0 RESPONSIBILITIES

The responsibilities of the QRA Pharmacist team includes

a. Evaluating held orders
b. Identifying suspicious orders
c. Reporting suspicious orders to DEA
d. Performing a review of suspicious orders
e. Releasing suspicious orders when appropriate

f. Cutting suspicious orders when appropriate

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC	The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.
Anti-Diversion Customer Profile	A report generated by QRA containing various background, licensing, and analytical metrics relevant to a customer used to assist in the evaluation of threshold events.
DEA Limit Over Threshold Report	An IT generated report generated by members of IT that contains all threshold events from a specified date.
Threshold	A quantity of dosage units for each controlled substance and monitored drug family that is established by QRA and is customer specific. The threshold is established to aid in monitoring ordering patterns and orders for large quantities of a monitored drug. An order that exceeds a threshold is not necessarily suspicious, but should be evaluated to determine if the order Is suspicious.
Threshold Event	The initial held order for a regulated drug which exceeds the threshold set for a specified customer. This is created by a DEA#, Base Code and Threshold Limit combination.

6.0 PROCEDURE

6.1 Initial Review

6.1.1 The following orders are held or cut pending review by QRA under this procedure

a. Orders of interest referred to by a distribution center
b. Orders that exceed a threshold set for the customer for the drug family

6.1.2 In addition, under this SOP, QRA can review other orders that may come to QRA's attention based on any other criteria.

6.1.3 Under this procedure, QRA must first review EVERY held or cut order under §6.1.1 to determine whether the order is suspicious as that term is used in 21 C.F.R. 1301.74(b). Per the regulation, orders are deemed suspicious if they meet one (1) or more of three (3) criteria:

a. Order is of unusual size
b. Order is of unusual frequency

c. Order deviates substantially from a normal pattern for the customer

6.1.4 Orders that meet one or more of the criteria in §6.1.3 must be reported to the DEA as suspicious.

6.1.5 **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.5.1 Orders of unusual size can be as a result of:

a. Unintentional order entry errors (including duplicate order entries)
b. Intentional orders placed by the customer

QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.

6.1.5.2 Unintentional order entry errors (including duplicate order entries) MUST NOT be reported as suspicious orders to DEA since the customer did not intend to place the order and MUST be cut with no changes to customer threshold and a readjustment of accrual to the level prior to the order entry error.

6.1.5.3 QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is deemed suspicious and MUST be reported to DEA.

6.1.6 **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.6.1 QRA personnel can use available information on order history and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order is of unusual frequency.

6.1.6.2 If the QRA personnel determines the order to be of unusual frequency then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.7 **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.

6.1.7.1 Substantial deviations in ordering patterns include, but are not limited to,

a. Orders for an unusually high percentage of controlled substances compared to non-controlled substances.
b. Orders for an unusually high percentage of a particular strength of drug that is known or suspected of being widely diverted.
c. Orders that are cumulatively larger than expected for the customer even though individual orders may not be unusually large.
d. Other deviations based on QRA personnel's experience.

6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.

6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.8 At the end of §6.1, the customers held or cut order under §6.1.1 will be found in one of the following states:

6.1.8.1 Orders cut due to order entry errors and NOT reported to DEA.

6.1.8.2 Held or cut orders reported as suspicious to DEA.

6.1.9 ALL orders reported to DEA as suspicious should undergo detail review set forth in Reference 1.

6.2 Review of Suspicious Orders

6.2.1 An order identified as a suspicious order at the end of §6.1.8 will undergo a detail review.

6.2.1.1 When the QRA personnel determines that the order will be released because the personnel has found that the drugs are unlikely to be diverted, the personnel must ensure that the reasons for releasing the order and relevant information considered have been recorded prior to releasing the order.

6.2.1.2 When the QRA personnel is unable to determine with information available that the order is not likely to be diverted:

a. The current order and subsequent orders in the same drug family will be held until a site visit is completed if a site visit is required under the Memorandum of Agreement or is otherwise deemed appropriate by the QRA pharmacist; or
b. The current order will be cut.

6.2.2 **Selection of a suitable type of site visit** (refer to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008.docx" } for conducting site visits)

6.2.2.1 For customers in Categories 1 and 2 (see Reference 2 for definition), one of the 3 types of site visits will be chosen based on factors including, but not limited to, the existing knowledge of the customer and availability of resources.

a. A site visit conducted by a qualified QRA personnel.
b. A site visit conducted by an independent investigator.
c. A site visit conducted jointly by a qualified QRA personnel and an independent investigator.

6.2.2.2 For customers in Categories 3, 4, and 5 (see Reference 2 for definition), a CAH employee or independent investigator will conduct the site visit.

6.2.3 **Decision based on findings of the site visit**

6.2.3.1 If the decision is to terminate the customer, the current order and subsequent orders in the same drug family will be cancelled (refer to [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" } for the decision making process).

6.2.3.2 If the decision is to retain the customer, the QRA personnel will:

a. Release the current and subsequent orders in the same drug family if the orders are not likely to be diverted or cut the held orders and continue to monitor the customer; and
b. Determine if the customer's threshold levels should be considered for adjustment and make adjustments if necessary following [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx" }.

7.0 DOCUMENTATION REQUIREMENTS

None

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Approvals

Approvals on file in the Pharmaceutical Distribution Corporate Document Center

Approvers: Nicholas Rausch

Owner: Danielle Holbrook
PDCDC Coordinator: Jason Paul Snouffer

Change History

DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3273	05 Mar 2013	Modify	No	Corporate	Other

Other (specify)

Training assignments to Corporate Anti-Diversion personnel who are involved in the detecting and reporting suspicious orders and responding to threshold events procedure.

Change Description and Justification

Section 6.2.1 of the SOP was updated to state that the "drugs are unlikely to be diverted" instead of the previously incorrect statement of "likely to be diverted."
Updated document owner to Danielle Holbrook.
Updated document approver to Nicholas Rausch.